US009101416B2

(12) **United States Patent**
Dunbar, Jr. et al.

(10) **Patent No.: US 9,101,416 B2**
(45) **Date of Patent: Aug. 11, 2015**

(54) **SPINAL ROD APPROXIMATOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1189 days.

(21) Appl. No.: **12/909,197**

(22) Filed: **Oct. 21, 2010**

(65) **Prior Publication Data**

US 2011/0034962 A1 Feb. 10, 2011

Related U.S. Application Data

(63) Continuation of application No. 10/761,036, filed on Jan. 20, 2004, now Pat. No. 7,887,539.

(60) Provisional application No. 60/442,208, filed on Jan. 24, 2003.

(51) **Int. Cl.**
A61B 17/70 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7091*** (2013.01); *A61B 17/7035* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/7091; A61B 17/7086; A61B 17/7083; A61B 17/7082; A61B 17/7076; A61B 17/7074
USPC .... 606/86 A, 99, 104, 914, 916; 81/451–453
See application file for complete search history.

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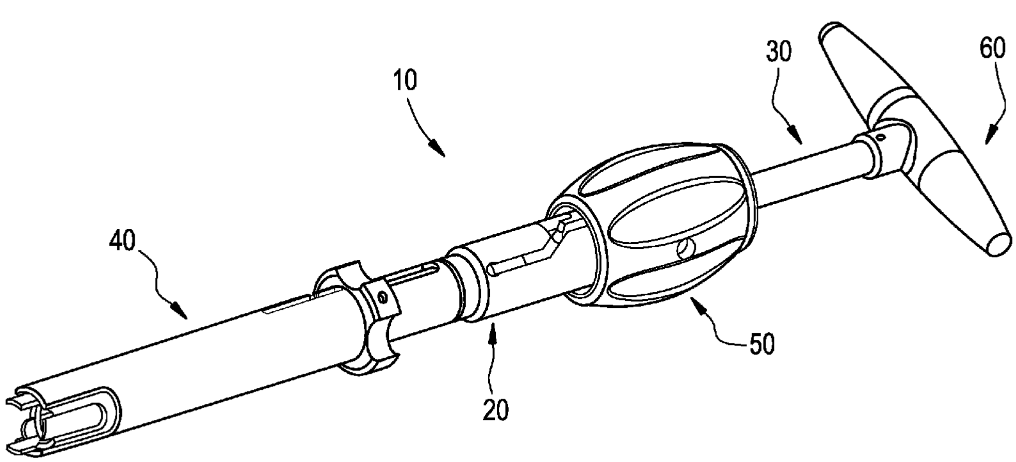
(57) **ABSTRACT**

Spinal rod approximator for seating a stabilizing rod in a rod-receiving portion of a spinal implant and inserting closure mechanism is provided. In one embodiment, a spinal rod approximator is provided including a body with gripping branches, inserter shaft, threaded collar, and outer sleeve.

9 Claims, 12 Drawing Sheets



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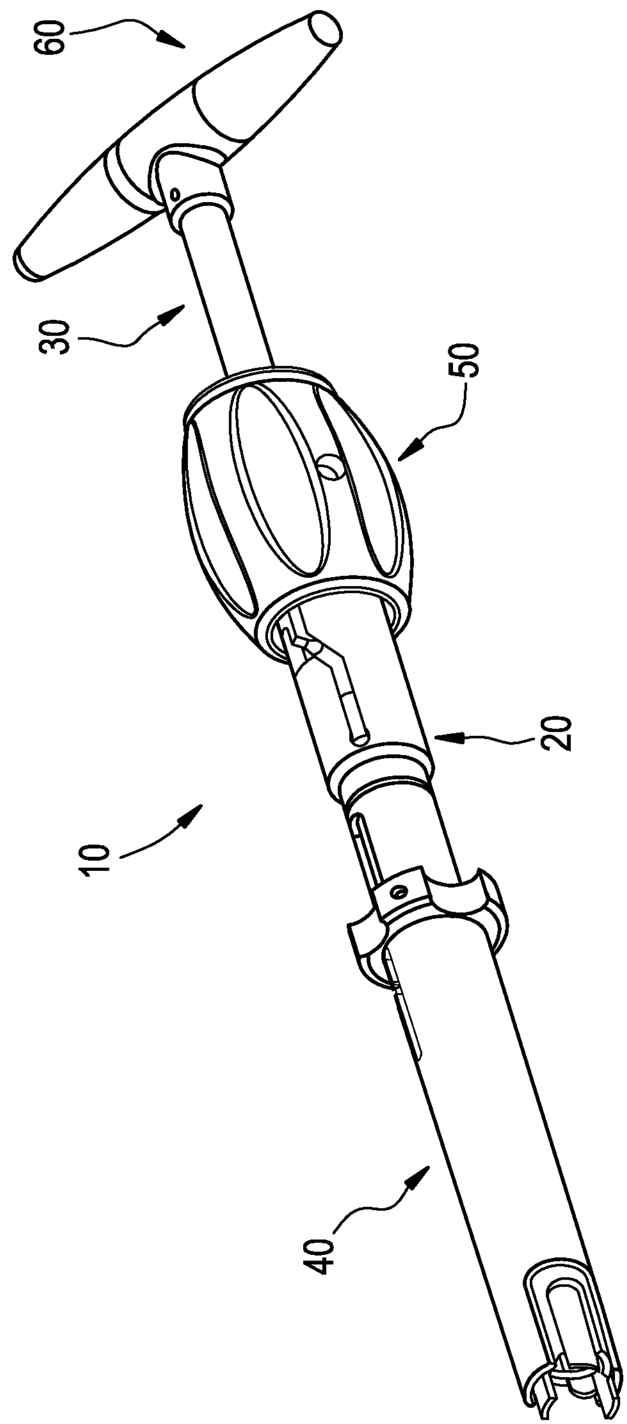


FIG. 1

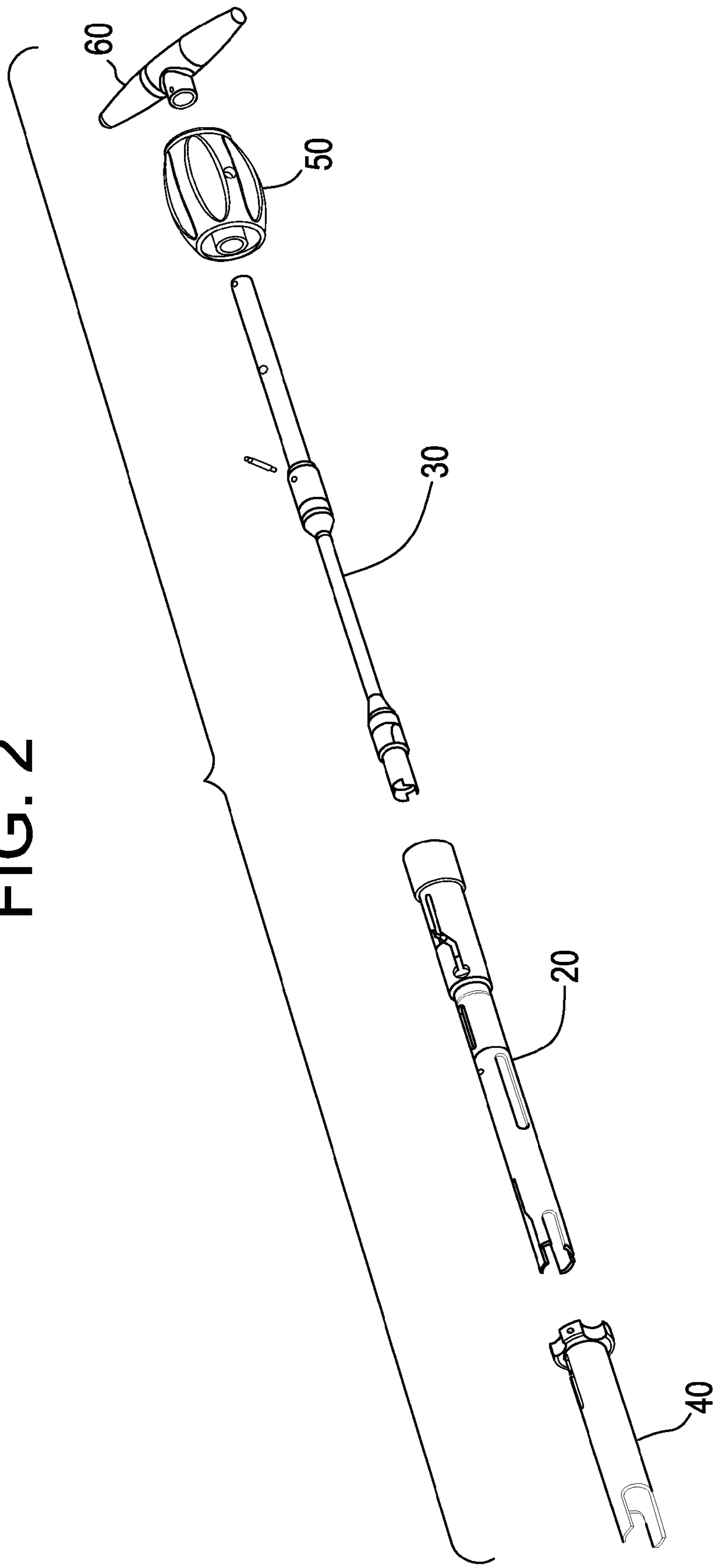


FIG. 2

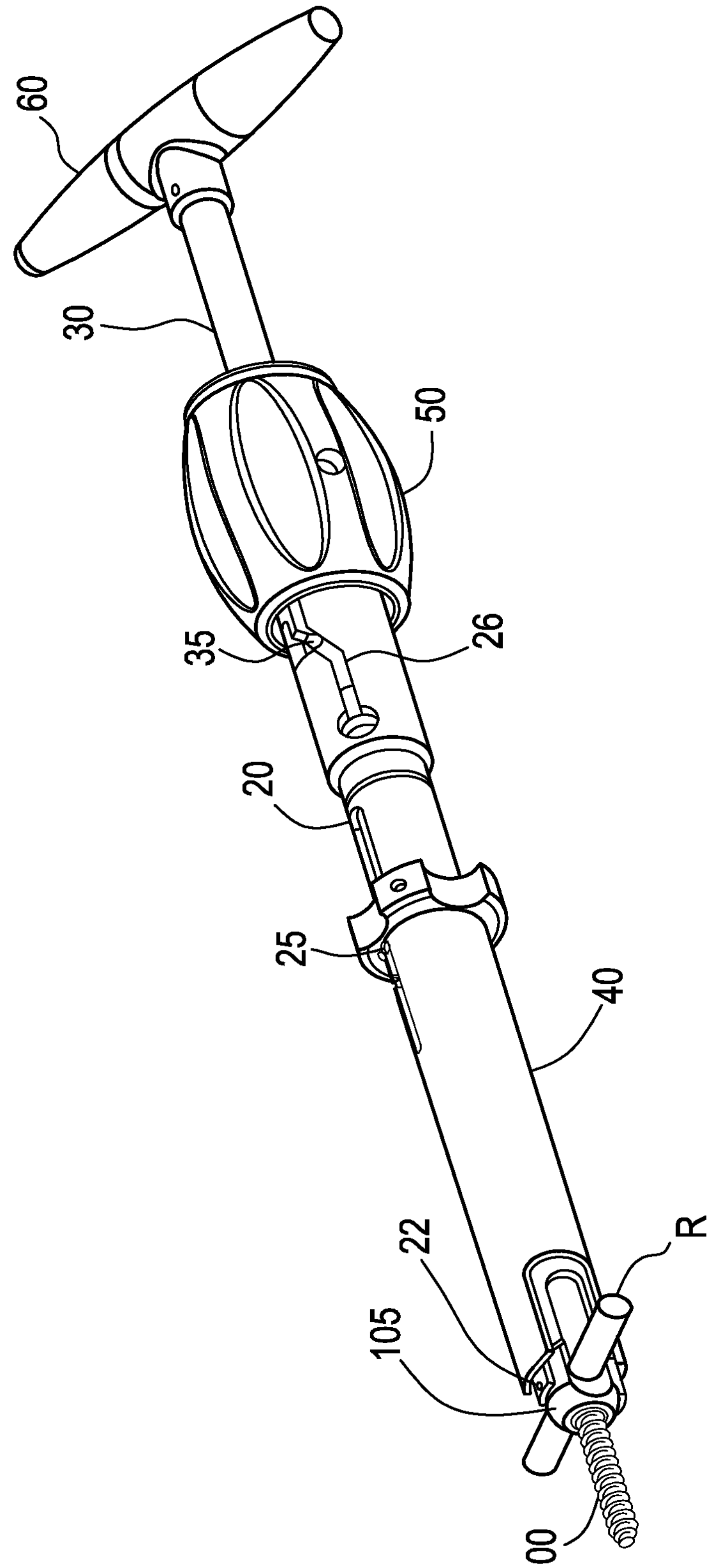


FIG. 3

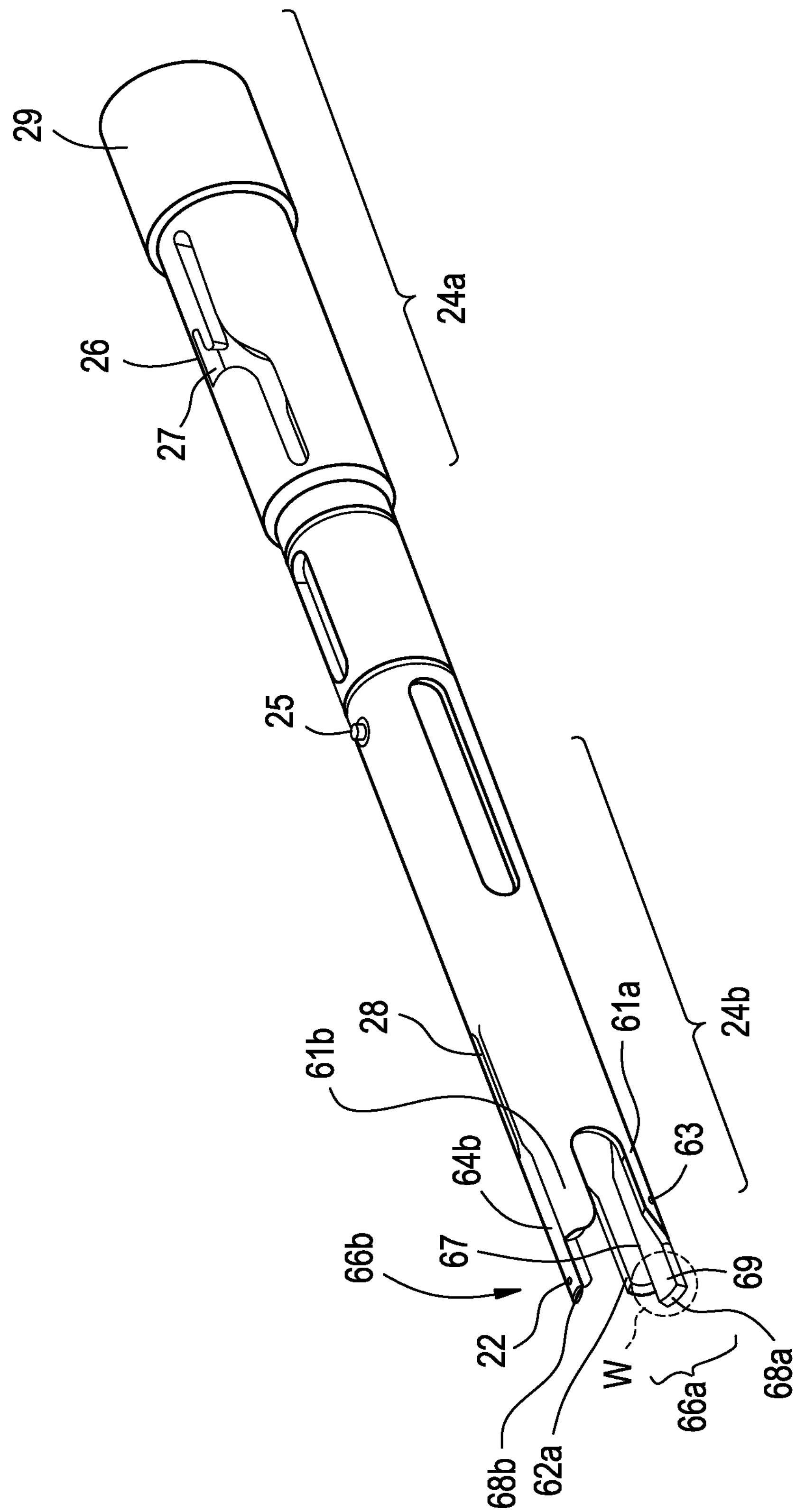


FIG. 4

FIG. 5A

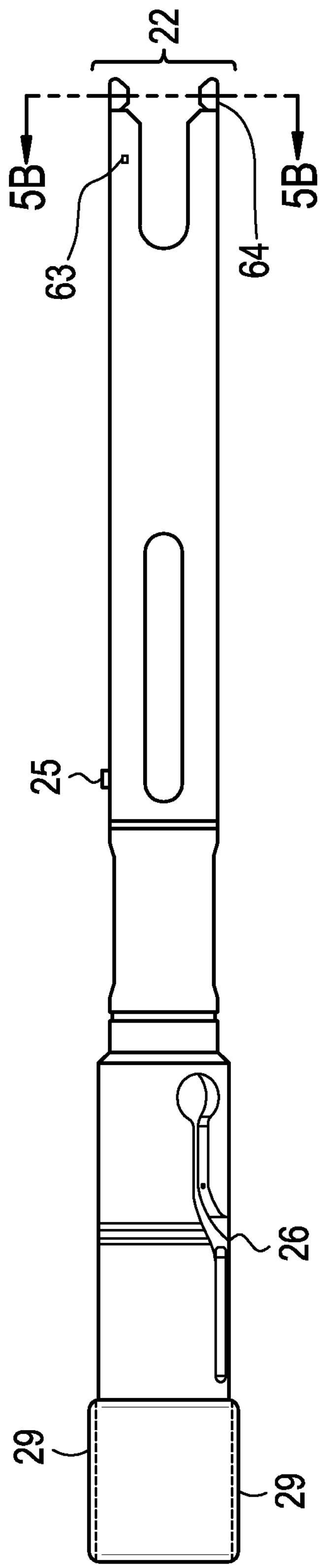


FIG. 5B

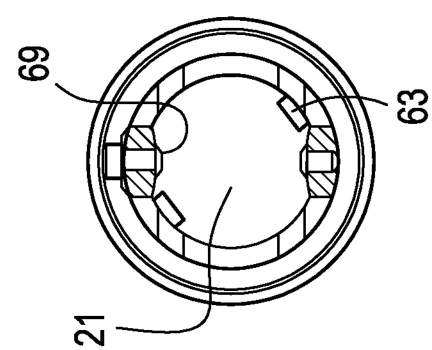
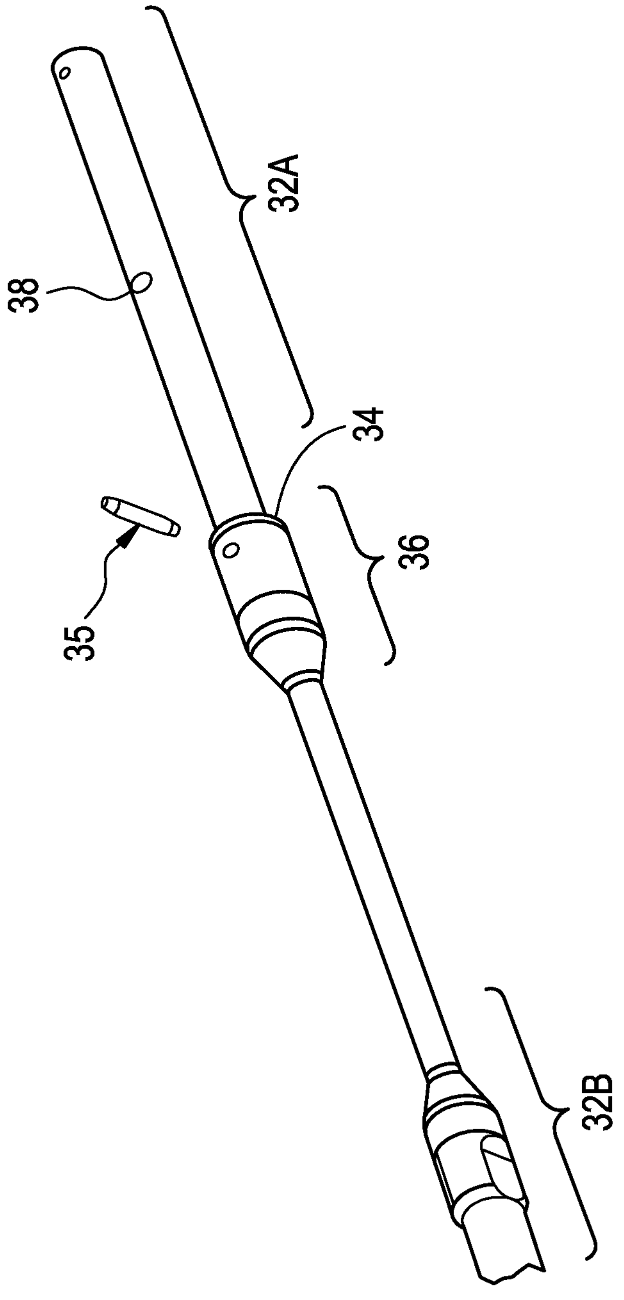


FIG. 6



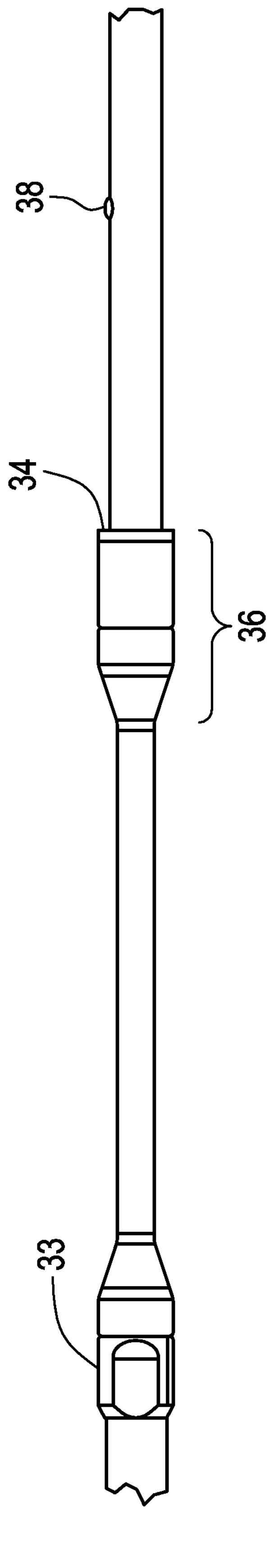


FIG. 6A

FIG. 7

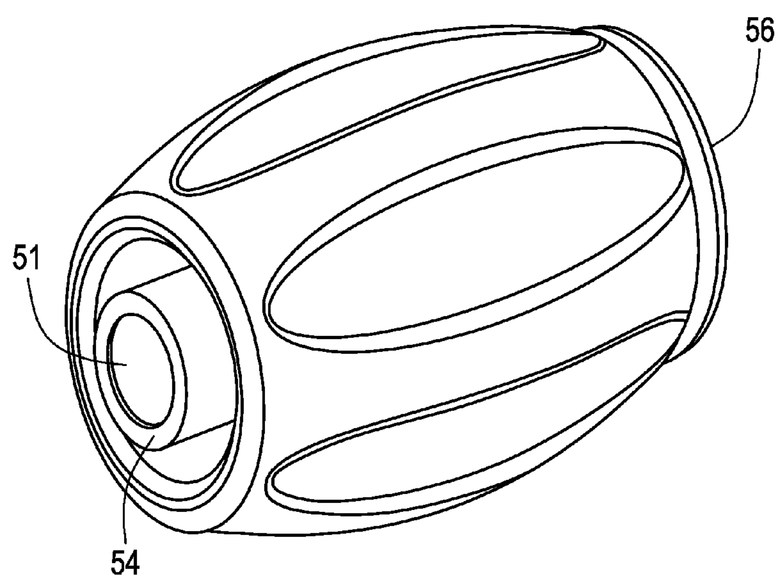


FIG. 7A

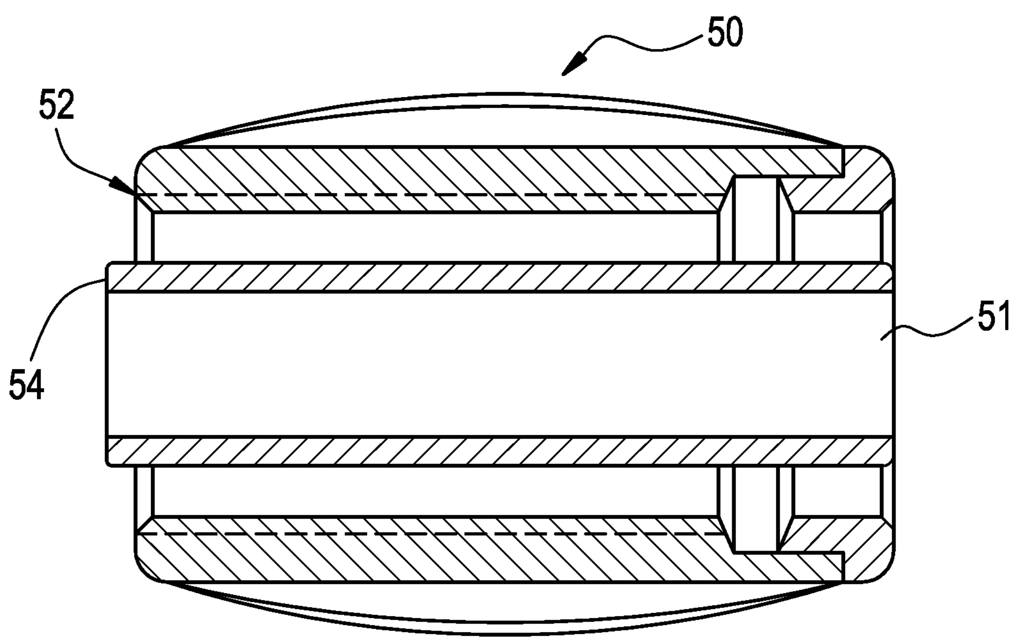


FIG. 8

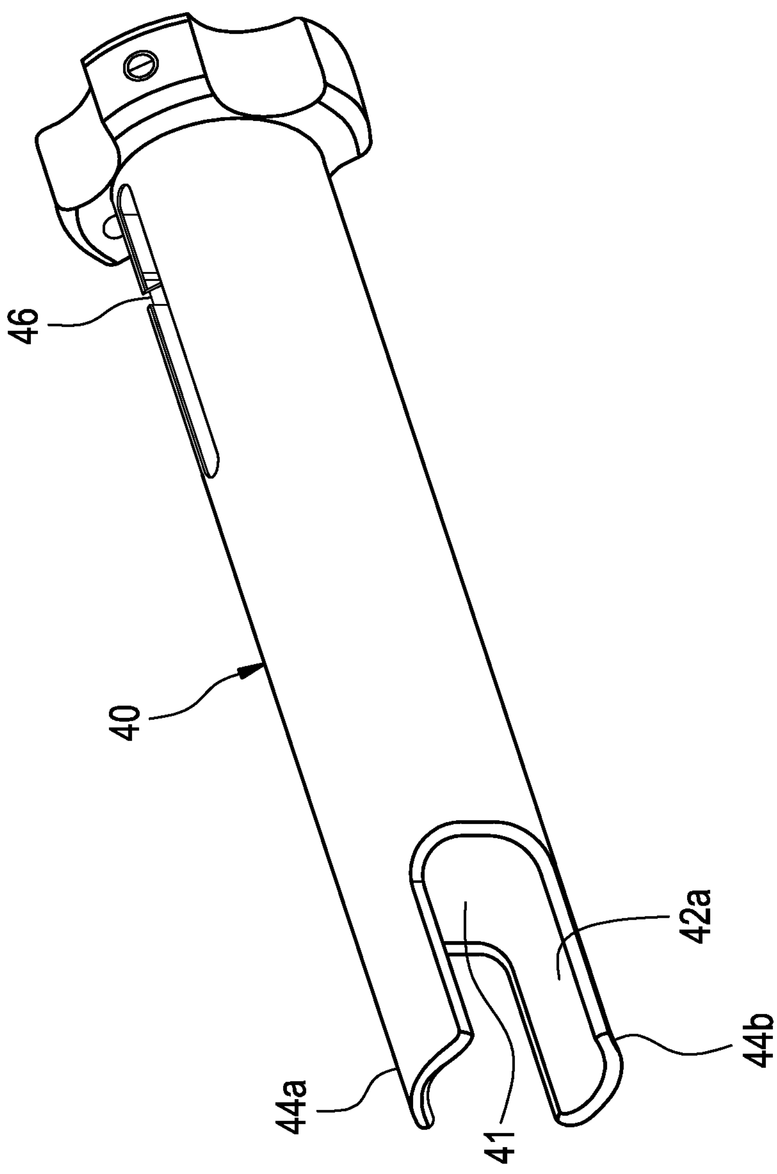


FIG. 9

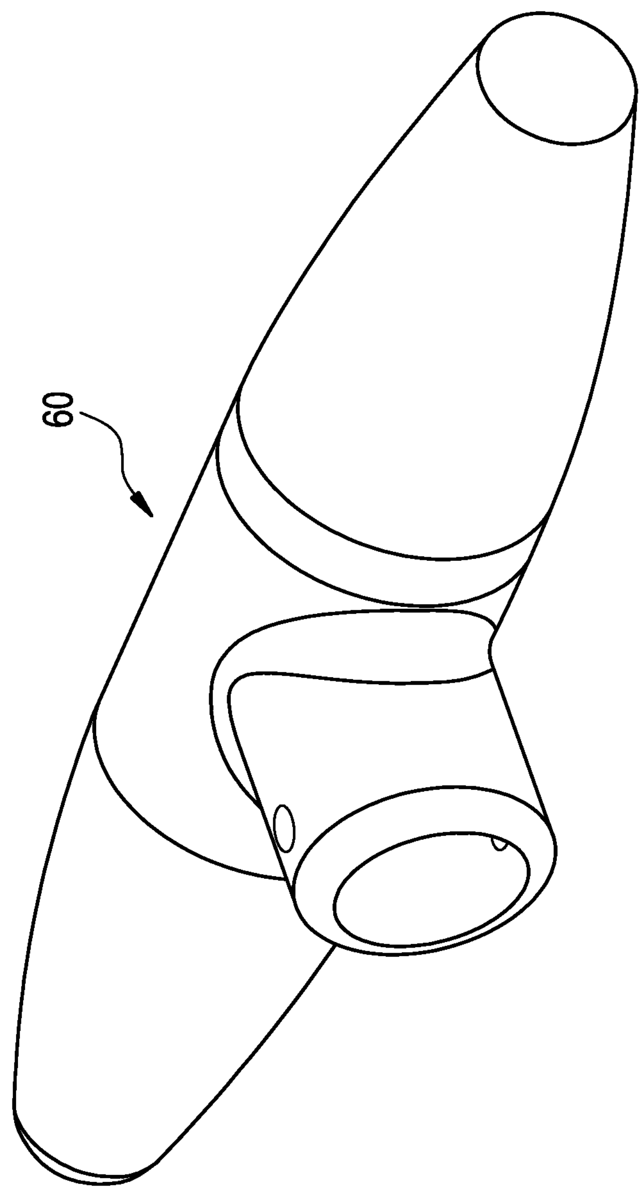


FIG. 10A

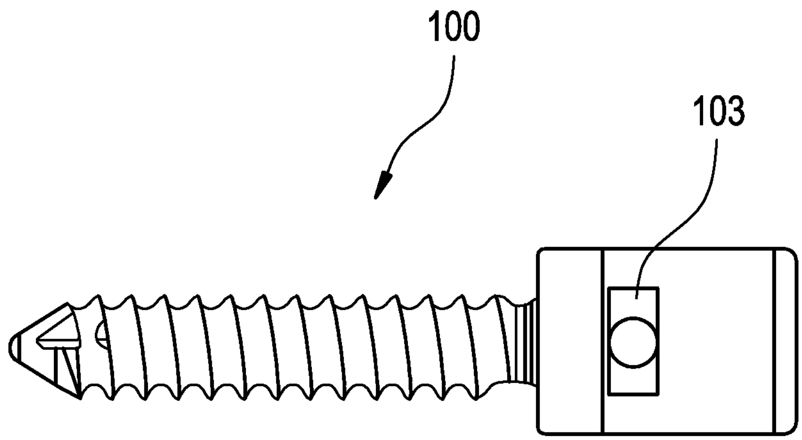
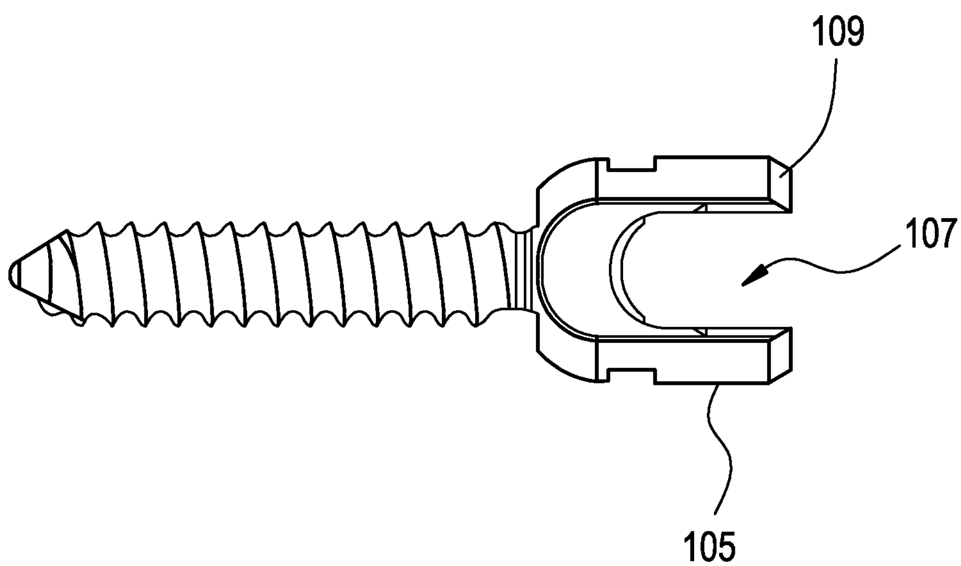


FIG. 10B



SPINAL ROD APPROXIMATOR

RELATED INVENTION

This application is a continuation of U.S. patent application Ser. No. 10/761,036, filed Jan. 20, 2004, which claims the benefit of U.S. Provisional Application No. 60/442,208, filed Jan. 24, 2003. Each of the aforementioned patent applications is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to spinal fixation systems, and in particular to a spinal rod approximator.

BACKGROUND

Spinal fixation devices are used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies. Such devices typically include a spinal fixation element, such as a relatively rigid fixation rod, that is coupled to adjacent vertebrae by attaching the element to various anchoring devices, such as hooks, bolts, wires, or screws. The rods can have a predetermined contour that has been designed according to the properties of the target implantation site, and once installed, the rod holds the vertebrae in a desired spatial relationship, either until desired healing or spinal fusion has taken place, or for some longer period of time.

Spinal fixation devices can be anchored to specific portions of the vertebra. Since each vertebra varies in shape and size, a variety of anchoring devices have been developed to facilitate engagement of a particular portion of the bone. Pedicle screw assemblies, for example, have a shape and size that is configured to engage pedicle bone. Such screws typically include a threaded shank that is adapted to be threaded into a vertebra, and a head portion having a rod-receiving element, usually in the form of a U-shaped slot formed in the head. A set-screw, plug, cap or similar type of closure mechanism, is used to lock the rod into the rod-receiving portion of the pedicle screw. In use, the shank portion of each screw is then threaded into a vertebra, and once properly positioned, a fixation rod is seated through the rod-receiving portion of each screw and the rod is locked in place by tightening a cap or similar type of closure mechanism to securely interconnect each screw and the fixation rod. Other anchoring devices also include hooks and other types of bone screws.

While current spinal fixation systems have proven effective, difficulties have been encountered in mounting rods into the rod-receiving portion of various fixation devices. In particular, it can be difficult to align and seat the rod into the rod receiving portion of adjacent fixation devices due to the positioning and rigidity of the vertebra into which the fixation device is mounted. Thus, the use of a spinal rod approximator, also referred to as a spinal rod reducer, is often required in order to grasp the head of the fixation device, and reduce the rod into the rod-receiving portion of the fixation device.

While several rod approximators are known in the art, some tend to be difficult and very time-consuming to use. Accordingly, there is a need for an improved rod approximator and methods for seating a spinal rod in a rod-receiving portion of one or more spinal implants.

SUMMARY

The present invention provides tools, medical devices and methods for seating a stabilizing rod in a rod-receiving portion of a spinal implant and inserting a closure mechanism for locking the rod to the spinal implant.

In one embodiment, the invention is directed to a tool for seating a spinal rod in a rod-receiving portion of a spinal implant. The tool has a body having a proximal end portion and a distal end portion. The distal end includes first and second flexible branches for gripping a spinal implant, such as a screw or hook. An inserter shaft having a distal end adapted to hold a closure mechanism for said implant is slidably received within the body. A threaded collar adapted to couple the body and inserter shaft such that the inserter shaft forces a spinal rod into the rod-receiving portion of the spinal implant. An outer sleeve is rotatably and slidably mounted onto the distal end of the body. The sleeve is movable between a first and second position wherein movement of the sleeve prevents the branches from spreading and separating from its grip on the implant.

In another embodiment the invention is directed to a method of seating a rod into a rod-receiving portion of a spinal implant. The steps include holding a tool having a body including first and second flexible branches for gripping the spinal implant, an inserter shaft slidably received within the body, the inserter shaft having a distal end adapted to hold a closure mechanism for the implant, and a threaded collar, adapted to couple the body and the inserter shaft. The operator slides the inserter shaft beyond the distal end of the body and attaches the closure mechanism. The closure mechanism is withdrawn into the body. The rod is positioned between the branches of the body. The flexible branches are expanded over the implant to securely grip the implant. The threaded collar is threaded onto the body advancing the inserter shaft and urging the rod into the implant. The inserter shaft is rotated to lock the closure mechanism to the spinal implant.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. **1** is perspective view illustration of an assembled spinal rod approximator according to one embodiment of the present invention;

FIG. **2** is an exploded view illustration of the components that are assembled to form the device shown in FIG. **1**;

FIG. **3** is a perspective view illustration of the device shown in FIG. **1** gripping a spinal implant and a spinal rod;

FIG. **4** is a perspective view illustration of the body of the device shown in FIG. **1**;

FIG. **5**A is a side view illustration of the body shown in FIG. **4**;

FIG. **5**B is a cross-sectional view illustration of the body shown in FIG. **4** taken from the distal end;

FIG. **6** is a perspective view illustration of the inserter shaft of the device shown in FIG. **1**;

FIG. **6**A is a cross-sectional view illustration of the inserter shaft shown in FIG. **6**;

FIG. **7** is a perspective view illustration of the threaded collar of the device shown in FIG. **1**;

FIG. **7**A is a cross-sectional view illustration of the threaded collar shown in FIG. **7**;

FIG. **8** is a perspective view illustration of the outer sleeve of the device shown in FIG. **1**;

FIG. **9** is a perspective view illustration of the T-handle of the device shown in FIG. **1**; and

FIGS. **10**A and **10**B are perspective illustrations of a typical spinal implant.

DETAILED DESCRIPTION OF THE INVENTION

In general, the present invention provides a spinal rod approximator for seating a stabilizing rod in a rod-receiving portion of a spinal implant. Typical spinal implants include pedicle screws (monoaxial and polyaxial), hooks, and other bone screws. The spinal rod approximator of the present invention is particularly effective in that it is easy to use, does not require significant force to operate, and is efficient, thereby reducing the time and expense necessary to perform spinal surgery.

In one embodiment, a rod approximator device is provided including a body for gripping the spinal implant, an inserter shaft for inserting the closure mechanism and seating the rod into the rod-receiving portion of the spinal implant, and a threaded collar for coupling the movements of the body and the inserter shaft. The device also includes an outer sleeve for locking the body to the spinal implant. The body has a gripping means located at its distal end effective to engage a spinal implant from the side or above. The inserter shaft fits within the interior channel of the body and is of sufficient length to extend beyond the body at the proximal and distal ends. The distal end of the inserter is adapted to grasp the closure mechanism. The outer sleeve is rotatably mounted around the outside of the body and is capable of sliding in a longitudinal direction along the axis of the body to prevent the gripping means from releasing the spinal implant during use of the tool.

The threaded collar couples the body and the inserter shaft such that as the collar is threaded along the body it pushes on the inserter shaft moving it through the body. The force generated by the threaded collar is effective to move the inserter shaft with the closure mechanism into contact with the rod and urge the rod into the rod-receiving portion of the spinal implant. Once the rod is seated into the spinal implant, the closure mechanism is locked into place by rotating the inserter shaft.

FIG. **1** illustrates the preferred embodiment of an assembled spinal rod approximator **10** that is effective to engage and seat a stabilizing rod in a rod-receiving portion of a spinal implant. FIG. **2** illustrates the individual components that are assembled to form the spinal rod approximator. As shown, the tool **10** generally includes a body **20** having a gripping means **22** on the distal end, an inserter shaft **30** for inserting the closure mechanism, an outer sleeve **40** for preventing the gripping means from releasing from the spinal implant during use, and a threaded collar **50** for coupling the inserter shaft to the body. The tool performs several actions during its use. As shown in FIG. **3** the tool **10** holds the closure mechanism of the spinal implant on the distal end of the inserter shaft **30** as the gripping means **22** on the body grip the head **105** of the spinal implant **100** while capturing the spinal rod R, the threaded collar **50** advances the inserter shaft **30** to seat the spinal rod into the rod-receiving portion of the spinal implant, rotation of the T-handle **60** of the inserter shaft inserts the closure mechanism and locks it into place within the head of the spinal implant. The channel **26** on the body allows the user to visualize the steps as they occur from outside the surgical site.

A person having ordinary skill in the art will appreciate that while the tools and devices illustrated herein are described for use with spinal surgery, the tools can be adapted for use with a variety of medical procedures.

The body **20** of the rod approximator **10** is shown in more detail in FIGS. **4** through **5**A. The body **20** can have a variety of shapes and sizes, but is preferably a generally longitudinal hollow tube having a proximal end portion **24***a* and a distal end portion **24***b*. The cross-sectional shape and size of the body **20**, as well as the length of the body **20**, can vary depending on the intended use. The body **20** should have a length sufficient to enable the distal end portion **24***b* of the body **20** to be placed adjacent a surgical site while the proximal end portion **24***a* of the body **20** remains outside a patient's body. By varying the size and shape, the body **20** can also be adapted for use in minimally invasive procedures.

The gripping means **22** include first and second branches **66***a*, **66***b* extending longitudinally from the distal end portion **24***b* of the body **20** and terminating in a distal end **68***a*, **68***b*. Each branch includes a flexible center **64***a*, **64***b* portion and two rigid side portions **60***a*, **62***a*, **60***b*, **62***b*. The center portion **64** is integrally formed from narrow slits **28** cut along the longitudinal axis of the distal end portion of the body. These slits provide the center portion the flexibility to expand around the implant head **105** to grip the implant and thus the slits permit branches **66***a* and **66***b* to be biased to a closed or gripping position. The center portion **64** forms the longest extension of the branch **66**. Front rigid side portions **60***a*, **60***b* extend from the distal end portion **24***b* of the body along the center portion and terminate a distance from the distal tip of the center portion. The back rigid side portions **62***a*, **62***b* also extend from the distal end portion of the body and terminate just before the distal end of the center portion. The front and back rigid side portions **60**, **62** form a substantially U-shaped recess to accommodate a spinal rod and spinal implant head. The distance d.sub.f from the distal end of the center portion **68** to the distal end of the front rigid side portion **60** is of sufficient length to allow the head of a spinal implant to pass through the channel to accommodate a side approach to gripping the spinal implant with the tool. The back rigid side portions **62** act as a stop to prevent the tool from completely passing over the spinal implant as the tool is gripping the implant from the side.

Preferably the interior surface **67** of each center portion **64** has a projection **69** for engaging a corresponding recess **103** located on the head of the spinal implant. Preferably a pin **63** projects from the interior surface **65** of the front rigid side portion **60**. The pin **63** acts as a stop engaging the top surface **109** of the implant to prevent the tool from sliding down over the entire spinal implant when using the tool to grip the implant from above. FIG. **5**A shows a cross-sectional view of the body **20** from the distal end. This view shows the interior channel **21** of the body and depicts the placement of the pins **63** and projections **69**.

Each branch **66***a*, **66***b* can have virtually any shape and size, and the branches can include several different mating features to facilitate grasping of the implant. As shown, the opposed branches **66***a*, **66***b* have a generally elongate, rectangular shape and include opposed inner surfaces **67***a*, **67***b*. The opposed inner surfaces each preferably have the same inner diameter which is designed to mate with the outer diameter of the head of the spinal implant. The projection **69** is located at the distal end of the inner surface. The distal most end of each center portion **68** can be rounded to prevent any potential damage to tissue surrounding the treatment site as the tool is used to grip the spinal implant. The projections **69** on the center portions and/or the head of the spinal implant can also include a variety of mating elements, including tongue-and-groove connections, dovetail connections, etc.

Along the proximal end portion **24***a* of the body is a guide mechanism which in the preferred embodiment takes the shape of a channel **26** to control the axial translation and rotational orientation of the inserter shaft **30** during operation of the instrument. The guide mechanism also allows the surgeon to visualize the steps of operation from outside the surgical site as they occur. The channel runs parallel to the longitudinal axis of the body. A portion of the channel **27** branches at an angle from the main portion of the channel and reverses direction. This portion of the channel controls the rotational orientation of the shaft with respect to the body and provides for proper alignment of the closure mechanism when locking to the implant and allows for releasing of the closure mechanism after locking. In the preferred embodiment this branch angles away from the main channel at approximately 90 degrees.

The proximal end portion of the body has external threads **29** to mate with the threads of the threaded collar **50**. The external threads **29** are illustrated in the side view of the body (FIG. **5**) as a dashed line. Between the distal end portion and the proximal end portion of the body a pin **25** extends outward for engaging the outer sleeve **40**.

Referring now to FIG. **6** the inserter shaft **30** is sized to be slidably received within the interior channel **210***f* the body **20** and coupled to the body **20** by the threaded collar **50**. The inserter shaft **30** can also have a variety of configurations, but is preferably a generally longitudinal body having a proximal end portion **32***a* and a distal end portion **32***b*. The length of the inserter shaft **30** can vary, but preferably the inserter shaft **30** has a length greater than the length of the body **20** such that it may extend beyond the distal and proximal ends of the body.

Located on the tip of the distal end portion **32***b* of the inserter shaft is the holder **33** for the spinal implant closure mechanism. The holder **33** can be adapted to hold the closure mechanism in a variety of ways. In the present invention the holder **33** uses a friction fit or press fit to hold the closure mechanism. By way of non-limiting example, the holder **33** can include flexible tabs (not shown) formed therein to snap onto the closure mechanism. A person having ordinary skill in the art will appreciate that virtually any holding technique can be used to engage the closure with the distal tip of the inserter shaft.

The proximal end portion **32***a* of the inserter shaft is connected to a T-handle **60**. Located between the proximal and distal ends of the inserter shaft is a transition zone **36** where the shaft transitions to a larger cross-sectional diameter from the distal portion of the shaft. At the proximal end of the transition zone is a shoulder **34** which the threaded collar **50** engages to reduce the spinal rod into the rod-receiving portion of the spinal implant. Projecting out from the transition zone is a pin **35** which is co operable with the channel **26** on the body **20** to control the axial translation and rotational orientation of the inserter shaft with respect to the body. The pin travels within the channel tracking the steps of the inserter shaft **30** as it grasps the spinal implant closure mechanism, pushes against the rod, inserts the closure mechanism and locks it into place. Since the pin is visible through the channel, the user is able to visualize these steps as they occur from outside the surgical site. Along the channel are markings which indicate to the user when to perform each of these steps. The tool is assembled with the pin captured within the channel such that the inserter shaft is not removable from the body. The length of the channel limits the distance that the inserter can translate within the body. The distance between the channel and the branched portion **27** of the channel limits the amount the inserter can rotate within the body. This distance corresponds to the amount of rotation necessary to lock the closure mechanism in place.

A person having ordinary skill in the art will appreciate that virtually any guiding technique can be used to guide the inserter shaft within the body. For example, the pin could be located on the body and engage a channel on the inserter shaft.

A projection **38** is located on the surface of the inserter shaft between the proximal end portion and the shoulder. Projection **38** rests against the rim **56** at the proximal end of the threaded collar to prevent the inserter shaft from sliding down and extending beyond the distal end of the body after the closure mechanism has been picked up and prior to gripping to implant.

Referring now to FIG. **7** and FIG. **7**A, threaded collar **50** has a hollow body with internal threads **52** adapted to engage the external threads **29** of the body **20**. Located within the threaded collar is a central shaft **51** having an internal diameter that is greater than the diameter of the proximal portion of the inserter shaft and less than the diameter of the shoulder **34** at the transition zone of the inserter shaft. The central shaft extends from the proximal end of the threaded collar. The distal rim **54** of the shaft projects beyond the distal end of the collar. The collar is rotatable and slidable along the proximal end portion of the inserter shaft **30** up to the transition zone. When the collar is advanced into contact with the body it is threaded onto the external threads **29** of the body **20**, such that the distal rim **54** of the center shaft engages the shoulder **34** of the inserter shaft **30** to push the closure mechanism held by the distal end **33** of the inserter shaft against a spinal rod to seat the rod in the rod-receiving portion of the implant.

Referring now to FIG. **8**, outer sleeve **40** is a hollow substantially cylindrical tube defining an interior channel **41** extending therethrough. The interior channel is sized to allow it to slide along the distal end portion **24***b* of the body **20** from a first to a second position. In the first position the outer sleeve is raised above the flexible center portion **64** of the branch **66** on the body such that the center portion **64** can expand to grip the implant. In the second position the outer sleeve locks the branches to the implant. The distal end of the outer sleeve has opposed U-shaped channels **42***a*, **42***b* configured to allow the tool **10** to capture a spinal rod above the head of the spinal implant while gripping the implant. The arms **44***a*, **44***b* located between the U-shaped channels are adapted to slide over the narrow slits **28** of the flexible center portions **64***a*, **64***b* when the sleeve is advanced to the second position to lock the branches to the implant. Pin **25** extending from the body projects into a channel **46** on the proximal end portion of the outer sleeve to couple the body and outer sleeve. The channel allows the outer sleeve to move from a first to a second position.

In use, one or more spinal implants **100** are screwed into vertebral bone structures. Typically, where two spinal implants **100** are fastened into adjacent vertebra, a spinal rod is inserted into the rod-receiving portion **107** of each implant. However, due to the alignment of the implants **100**, it can be difficult to position the rod within each rod-receiving recess **107**. Thus, a rod approximator device is necessary. In use, the outer sleeve is raised in the first position as the spinal rod approximator **10** picks up and retains the spinal implant closure mechanism in the distal end portion **24***b* of the inserter shaft. The pin on the inserter shaft is visible at the distal end of the channel when the inserter shaft is advanced to pick up the closure mechanism. The pin travels back up the channel to the distal end of the channel when the inserter shaft **30** is retracted inside the body **20** above the U-shaped channels **42***a*, **42***b* of the outer sleeve. At this position the projection **38** rests against the rim **56** of the threaded collar.

The tool **10** approaches the head of the spinal implant from above or the side. The flexible center portions **64** of the branches expand to slide over the implant head and spring back to their original position to grip the recesses **103** on the outside of the spinal implant head **105**. The outer sleeve **40** slides down into the second position preventing the branches from spreading and disengaging the grip on the implant. The threaded collar **50** is turned to engage the external threads **29** on the body **20** such that the rim **54** of the threaded collar abuts the shoulder **34** of the inserter shaft **30** and advances the shaft. The closure mechanism held in the distal end of the inserter shaft contacts the spinal rod, forcing the rod into the rod-receiving portion **107** of the spinal implant. As the inserter shaft advances axially, the pin follows the channel until it reaches the portion **27** of the channel that branches off at an angle. The pin reaches this position when the rod is seated in the implant. At this point the closure mechanism is properly aligned and the T-handle **60** of the inserter shaft is rotated to insert and lock the closure mechanism into the head of the spinal implant. The inserter shaft is pulled up to disengage the closure mechanism from the holding end and the outer sleeve is slid back to the first position so that the branches of the body are permitted to expand and disengage from the implant simply by pulling the device away from the implant.

One of ordinary skill in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A tool for seating a spinal rod in a rod-receiving portion of a spinal implant, the tool comprising:

a body having a proximal end and a distal end, the distal end of the body including a first and second flexible branch for gripping a spinal implant, the flexible branches being spaced-apart a distance to form a first recess, the first recess opening at an end of the distal end of the body and extending proximally from the end;

an inserter shaft slidably received within the body, the inserter shaft having a distal end adapted to hold a closure mechanism for the implant, the inserter shaft having a proximal end, a distal end, and a transition zone located between the distal and proximal end, the transition zone having a diameter larger than the proximal end of the shaft;

a threaded collar, adapted to couple the body and the inserter shaft, wherein the inserter shaft forces a spinal rod into the rod-receiving portion of the implant; and

an outer sleeve mounted about the distal end of the body and movable between a first position and a second position in which the outer sleeve surrounds the branches to inhibit separation of the first and second flexible branches, the outer sleeve including a pair of spaced-apart arms at a distal end of the outer sleeve, the arms of the outer sleeve defining a second recess, the second recess aligning with the first recess of the distal end of the body when the outer sleeve is in the second position to accommodate a spinal rod within the first recess and the second recess.

2. The tool of claim **1**, wherein the first recess is substantially U-shaped.

3. The tool of claim **1**, wherein the outer sleeve is rotatably and slidably mounted about the distal end of the body.

4. The tool of claim **1**, wherein the flexible branches are biased to a closed position.

5. A spinal instrument comprising:

a body having a proximal end and a distal end, the distal end including a first branch and a second branch for gripping a spinal implant, the branches being spaced-apart a distance to form a first recess, the first recess opening at an end of the distal end and extending proximally from the end;

an inserter shaft slidably received within the body, the inserter shaft having a distal end adapted to hold a closure mechanism for the implant, the inserter shaft having a proximal end, a distal end, and a transition zone located between the distal and proximal end, the transition zone having a diameter larger than the proximal end; and

an outer sleeve mounted about the distal end of the body and movable between a first position and a second position in which the outer sleeve surrounds the branches to inhibit separation of the first and second branches, the outer sleeve including a pair of spaced-apart arms at a distal end of the outer sleeve, the arms of the outer sleeve defining a second recess, the second recess aligning with the first recess of the distal end of the body when the outer sleeve is in the second position to accommodate a spinal rod within the first recess and the second recess.

6. The spinal instrument of claim **5**, wherein the first branch includes a free distal end and a proximal end flexibly connected to the body and the second branch includes a free distal end and a proximal end flexibly connected to the body.

7. The spinal instrument of claim **6**, wherein the first and second branches are biased to a position in which the first branch is parallel to the second branch.

8. The spinal instrument of claim **5**, wherein the first recess is substantially U-shaped.

9. The spinal instrument of claim **8**, wherein the second recess is substantially U-shaped.

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